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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,001	04/21/2000	Joan C. Egric	A-460A	1458

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EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,001

Applicant(s)

EGRIE ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/9/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14, 18-22, 29, 30 and 32-44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 27 is/are allowed.
- 6) ☒ Claim(s) 11-13, 15-17, 24-26, 28 and 31 is/are rejected.
- 7) ☒ Claim(s) 28 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of Application, Amendments and/or Claims

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647, Regina M. DeBerry.

The amendment filed 21 April 2000 (Paper No. 4) has been entered in full. The information disclosure statement and supplementary information disclosure statement filed 24 June 2000 (Paper No. 5) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Applicant's election with traverse of Group II (claims 11-13, 15-17, 23-28 and 31) in Paper No. 10 is acknowledged. The traversal is on the grounds that the claims of Group II are dependent on claims drawn to methods of raising and maintaining hemacrit and therefore comprise certain embodiments of the methods corresponding to Group I. The claims of Group I and Group II are related as product and process of use. EPO compositions, however, can be used in other processes such as making antibodies and identifying EPO binding protein. Thus, the inventions of Group I and Group II are distinct. The requirement is still deemed proper and is therefore made FINAL. Claims 1-10, 14, 18-22, 29, 30, 32-37, 38-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Specification

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

Claim Objections

Claims 28 and 31 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the previous claim in the alternative. See MPEP § 608.01(n). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13, 15-17 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims depend on claims drawn to a non-elected group and it is unclear which limitations of the recited methods are incorporated into the claimed analogs/compositions under consideration. Appropriate correction is required. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13, 24-26, 28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Elliott *et al.* (WO 95/05465), IDS #BC. The instant claims are generally drawn to hyperglycosylated analogs of erythropoietin wherein the carbohydrate chain is an N-linked carbohydrate chain at one or more positions 30, 51, 57, 69, 88, 89, 136 and 138 of human erythropoietin. Elliott *et al.* teach carbohydrate attachments of asparagine residues (N-linked) at positions 30, 51, 57, 69, 88, 89, 136 and 138 in the human erythropoietin amino acid sequence (page 15, lines 16-33 and page 56 Table 6). Elliott *et al.* therefore teach at least four additional glycosylation sites wherein a carbohydrate chain is attached to each of the sites. Elliott *et al.* teach additional N-linked carbohydrate chains at position 30 and 88 of the human erythropoietin sequence (page 18, lines 4-10). Elliott *et al.* teach Asn30Thr32Val87Asn88Thr90 Epo (page 44 Table 3, page 48, lines 5-6, page 49, lines 26-30 and page 56 Table 6). Elliott *et al.* teach DNA sequences encoding such erythropoietin analogs, recombinant plasmids and host cells for analog expression (page 5, lines 22-25). Elliott *et al.* also teach pharmaceutical compositions comprising a therapeutically effective amount of an erythropoietin analog together with a suitable diluent, adjuvant and/or carrier (page 20, lines 23-36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott *et al.* (WO 95/05465), IDS #BC in view of Yoshitomi *et al.* US Patent No. 5,555,093.

Elliott *et al.* teach carbohydrate attachments of asparagine residues (N-linked) at positions 30, 51, 57, 69, 88, 89, 136 and 138 in the human erythropoietin amino acid sequence (page 15, lines 16-33 and page 56 Table 6). Elliott *et al.* teach additional N-linked carbohydrate chains at position 30 and 88 of the human erythropoietin sequence (page 18, lines 4-10). Elliott *et al.* teach Asn30Thr32Val87Asn88Thr90 Epo (page 48,

lines 5-6, page 49, lines 26-30 and page 56 Table 6). Elliott *et al.* also teach pharmaceutical compositions comprising a therapeutically effective amount of an erythropoietin analog together with a suitable diluent, adjuvant and/or carrier (page 20, lines 23-36). Elliott *et al.* do not teach a buffer solution of sodium citrate as a diluent, human serum albumin as a carrier or benzyl alcohol as a preservative.

Yoshimito *et al.* teach administering a platelet-increasing agent (hst-1). Yoshimito *et al.* teach that hst-1 can be administered in combination with other platelet increasing agents such as erythropoietin (column 8, lines 8-22). Yoshimito *et al.* teach pharmaceutical compositions, pharmaceutical acceptable additives, diluents or excipients (column 8, lines 28-31). Yoshimito *et al.* teach the use of sodium citrate, human serum albumin and benzyl alcohol (column 8, lines 31-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of hyperglycosylated erythropoietin analogs taught by Elliott *et al.* and the use of sodium citrate, human serum albumin and benzyl alcohol taught by Yoshimito *et al.* The motivation and expected success comes from the benefits of stabilizing/preserving, antibacterial action and proper buffering (pH) of hyperglycosylated erythropoietin analogs which is provided by using sodium citrate, human serum albumin and benzyl alcohol.

Allowable Subject Matter

Claims 23 and 27 would be allowed.

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD

February 15, 2002

Elizabeth C. Zimmerman

ELIZABETH C. ZIMMERMAN
PRIMARY EXAMINER